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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER ...

KAUFMAN, CLAIRE M

ART UNIT PAPER NUMBER

1646

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 98-105 and 120-144, drawn to nucleic acid, vector, host cell and method of recombinantly producing the encoded polypeptide, classified in class 536, subclass 23.5.
- II. Claims 106-109, drawn to polypeptide, classified in class 530, subclass 350.
- III. Claims 110-119, drawn to antibody, classified in class 530, subclass 388.22.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acid of Invention I is related to the protein of Invention II by virtue of encoding the same. The nucleic acid has utility for the recombinant production of the protein in a host cell, as recited in claim 105, for example. Although the nucleic acid and protein are related since the nucleic acid encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthesis or purification from the natural source. Further, the nucleic acid may be used for processes other than the production of the protein, such as nucleic acid hybridization assay to identify structurally related nucleic acids and *in situ* hybridization to localize the nucleic acid.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). Even though the nucleic acid of Invention I encodes the protein to which the antibody of Invention III binds, in the instant case the different inventions are not used together and have different modes of operation. The nucleic acid does not encode the antibody and the antibody cannot bind the nucleic acid.

The protein of Invention II is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibody. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because the protein can be used for another and materially different process other than for production of the antibody, such as in a pharmaceutical composition in its own right, or to

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assay or purify the natural ligand of the protein (as the protein is itself a receptor), or in assays for the identification of agonist or antagonists of the receptor protein.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, have recognized divergent subject matter, and because each invention requires a separate non-coextensive search, restriction for examination purposes as indicated is proper.

A telephone call was made to Elizabeth Haanes on March 27, 2006, to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found

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allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571) 272-0873. Dr. Kaufman can generally be reached Monday, Tuesday, Thursday and Friday from 9:30AM to 2:30PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Official papers filed by fax should be directed to (571) 273-8300. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

April 4, 2006